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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,084	01/26/2006	Julien Meissonnier	03762.015900	1166

74432 7590 11/02/2010

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
11/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,084	MEISSONNIER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action and Applicant's Arguments/Remarks, filed 08/19/10 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of persuasive remarks: (1) The 35 U.S.C. §112, second paragraph rejection of claim 10 has been withdrawn.

Claims 1-15 are pending in this action. No amendments to the claims have been made. Claims 10-14 are currently under consideration. Claims 1-9 and 15 remain withdrawn (based on non-elected invention). Claims 10-14 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson *et al.* (hereinafter "Hutchinson") (U.S. Pat. No. 5,817,323).

Hutchinson ('323) teaches soft gelatin capsule shell compositions. The compositions comprise as the shell material, gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and a further component compatible with the gelatin, such as unbleached starch acetate, another starch derivative, starch itself or mixtures thereof, whereby the further component is normally no more than 12% (see column 1, lines 1-59); (col. 2, lines 17-30). The chewability of the compositions can be enhanced by inclusion of an oil (i.e., coconut oil). Oil disperses within the shell structure as microscopic droplets (col. 2, lines 31-46). Suitable hydrophobic solvent/carrier media components are discussed at column 5, lines 32-42). Hutchinson teaches that where the encapsulated contents include particles in suspension, the particles may be separately coated, typically with suitably sweetened or flavored coatings. Such a coating can serve as either or both of a taste-masking agent and a stabilizer in the suspension (col. 5, lines 61-67).

With respect to the amounts/ranges of the ingredients in claim 13 (i.e., gelatin, plasticizer, etc.), the amounts and ranges disclosed by Ebert meet and/or overlap with the amounts/ranges as

instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

While the references do not explicitly teach that the lipophilic vehicle has a "solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", the Hutchinson reference, nonetheless teaches active substances embedded within a fill composition that is comprised of the same components, namely, hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions. The solubility characteristics or solubilization power would be expected to be similar if not the same based on incorporation of the same ingredients under similar conditions, absent a showing of evidence to the contrary. Moreover, it would be well within the purview of the skilled artisan at the time the invention was made to adjust the solubilizing power or solubility characteristics by routine or manipulative experimentation during the capsule formulation process.

The instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Hutchinson.

* * * * *

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas *et al.* (hereinafter "Douglas") (U.S. Pat. No. 5,635,200) in view of Hutchinson *et al.* (hereinafter "Hutchinson") (U.S. Pat. No. 5,817,323).

Douglas ('200) teaches chewable soft gelatin capsules comprising (a) a dispersion of lipid coated particles of ranitidine or an acceptable salt thereof in a non-aqueous vehicle; (b) particles comprising ranitidine or an acceptable salt thereof incorporated into a core and coated with a lipid coating; c) lipid coated particles in the form of ranitidine which is poorly soluble in water (see Abstract); (col. 2, lines 8-24).

. The bitter taste may be masked by coating the drug substance with a suitable lipid (col. 1, lines 50-67). The pharmaceutical composition can be in the form of chewable soft gelatin capsules (col. 6, lines 39-45).

Douglas does not teach the shell components (gelatin, plasticizer, starch) in the amounts claimed.

Hutchinson ('323) teaches soft gelatin capsule shell compositions. The compositions comprise gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and a further component compatible with the gelatin, such as unbleached starch acetate, another starch derivative, starch itself or mixtures thereof, whereby the further component is normally no more than 12% (see column 1, lines 1-59); (col. 2, lines 17-30). The chewability of the compositions can be enhanced by inclusion of an oil (i.e., coconut oil) and plasticizers. Oil disperses within the shell structure as microscopic droplets (col. 2, lines 17-46). Suitable hydrophobic solvent/carrier

media components are discussed at column 5, lines 32-42). Hutchinson teaches that where the encapsulated contents include particles in suspension, the particles may be separately coated, typically with suitably sweetened or flavored coatings. Such a coating can serve as either or both of a taste-masking agent and a stabilizer in the suspension (col. 5, lines 61-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the shell components (gelatin, plasticizer, starch) in the amounts as claimed by Hutchinson within the capsules of Douglas. One would do so with a reasonable expectation of success because Hutchinson explicitly teaches that the chewability of the capsules can be enhanced by inclusion of an oily component and plasticizers and teaches that their drug particles may be separately coated, typically with suitably sweetened or flavored coatings, in order to provide for taste-masking effects as well as to impart stability to the capsule composition. Based on the modification of Douglas by Hutchinson, the expected result would yield an improved soft chewable capsule having enhanced stability and taste-masking effects.

With respect to the amounts/ranges of the ingredients in claim 13 (i.e., gelatin, plasticizer, etc.), the amounts and ranges disclosed by Hutchinson meet and/or overlap with the amounts/ranges as instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

While the references do not explicitly teach that the lipophilic vehicle has a "solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", the Hutchinson reference, nonetheless teaches active substances embedded within a fill composition that is comprised of the same components, namely, hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions. The solubility characteristics or solubilization power would be expected to be similar if not the same based on incorporation of the same ingredients under similar conditions, absent a showing of evidence to the contrary. Moreover, it would be well within the purview of the skilled artisan at the time the invention was made to adjust the solubilizing power or solubility characteristics by routine or manipulative experimentation during the capsule formulation process.

Hence, the instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the combined teachings of Douglas and Hutchinson.

* * * * *

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (hereinafter "Ebert") (U.S. Pat. No. 4,532,126) in view of Hutchinson *et al.* (hereinafter "Hutchinson") (U.S. Pat. No. 5,817,323).

Ebert ('126) teaches a chewable, filled, one-piece soft elastic gelatin (SEG) capsule and method for its manufacture, wherein the SEG capsule is formed from a formulation of gelatin (about 10-90 % by wt.), water (about 5-40 % by wt.), a plasticizer (e.g., sorbitol) and a masticatory substance and taste modifiers (about 0-10 % by wt.). The gelatin is present in the shell and incorporates a fill material contained within the shell, whereby the fill material may be selected from a variety of materials including candy, confectionaries, antacids, cough and cold preparations, sore throat remedies, antiseptics and dental preparations, such as fluorides, breath fresheners and the like. Conventional SEG capsules comprising gelatin have a bloom value of about 150-200, although this value may be varied (see Abstract); (column 1, line 60 – col. 2, line 68).

In manufacturing the SEG capsules, a molten gel mass is prepared with a dispersion of a molten masticatory substance therein. A suitable fill material is also prepared. The gelatin formulation containing the masticatory substance dispersed therein is formed as a shell around the fill material. The capsules are dried until the desired chewing characteristics are attained (Abstract); (col. 2, lines 46-53).

Suitable taste modifiers or flavorings added to the fill composition, the gelatin composition or in both simultaneously and can be selected from cherry syrup, citric acid, dextrose, essential oil (i.e., clove, lemon, orange, peppermint, spearmint), ethyl vanillin, glucose, honey, mannitol, methyl salicylate, raspberry syrup, saccharin, saccharin sodium, sorbitol, sucrose, wild cherry syrup and mixtures thereof (col. 4, lines 13-26). The gelatin capsules are formed into any desired shape, color and size (col. 4, lines 35-42).

With respect to the amounts/ranges of the ingredients in claim 13 (i.e., gelatin, plasticizer, etc.), the amounts and ranges disclosed by Ebert meet and/or overlap with the amounts/ranges as instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Ebert does not teach coated crystals or granules of active agent in a lipophilic vehicle.

Hutchinson ('323) teaches soft gelatin capsule shell compositions. The compositions comprise gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and a further component compatible with the gelatin, such as unbleached starch acetate, another starch derivative, starch itself or mixtures thereof, whereby the further component is normally no more than 12% (see column 1, lines 1-59); (col. 2, lines 17-30). The chewability of the compositions can be enhanced by inclusion of an oil (i.e., coconut oil). Oil disperses within the shell structure as microscopic droplets (col. 2, lines 31-46). Suitable hydrophobic solvent/carrier media components are discussed at column 5, lines 32-42). Hutchinson teaches that where the encapsulated contents include particles in suspension, the particles may be separately coated, typically with suitably sweetened or flavored coatings. Such a coating can serve as either or both of a taste-masking agent and a stabilizer in the suspension (col. 5, lines 61-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the coated drug particles that are provided in a hydrophobic (lipophilic) vehicle as taught by Hutchinson within the capsules of Ebert. One would do so with a reasonable expectation of success because Hutchinson explicitly teaches that the chewability of the capsules can be enhanced by inclusion of an oily component and teaches that their drug particles may be separately coated, typically with suitably sweetened or flavored coatings, in order to provide for taste-masking effects as well as to impart stability to the capsule composition. In addition, Ebert discloses a gelatin capsule comprising gelatin, water and taste-modifiers or flavorings, whereby the capsule comprises a fill material containing various ingredients, including medicaments, candies and confectionaries. The reference recognizes the importance of avoiding unpleasant taste upon breakage of the capsule shell in order to release the fill components. The avoidance of unpleasant taste is particularly significant for fill components comprising medicaments or therapeutic agents, which generally are known to exhibit poor taste. Based on the modification of Ebert by Hutchinson, the expected result would yield an improved soft chewable capsule having enhanced stability and taste-masking effects.

While the references do not explicitly teach that the lipophilic vehicle has a "solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", the Hutchinson reference, nonetheless teaches active substances embedded within a fill composition that is comprised of the same components, namely, hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions. The solubility characteristics or solubilization power would be expected to be similar if not the same based on incorporation of

the same ingredients under similar conditions, absent a showing of evidence to the contrary. Moreover, it would be well within the purview of the skilled artisan at the time the invention was made to adjust the solubilizing power or solubility characteristics by routine or manipulative experimentation during the capsule formulation process.

Hence, the instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the combined teachings of Ebert and Hutchinson.

* * * * *

Response to Arguments

Applicant's arguments filed 08/19/10 have been fully considered and were found to be partially persuasive.

- **Claim Rejections - 35 USC § 112:**

Applicant argued, "Applicants submit that one of ordinary skill in the art reading the specification and claims of the subject application would readily understand the meaning of the phrase. Specifically, it relates to the concentration at which the taste of the active is detected. Further, the meaning is explained at page 6, line 13 through page 7, line 5 of the subject specification as filed."

Applicant's arguments have been fully considered and were found to be persuasive. Accordingly, the 35 U.S.C. §112, second paragraph rejection of claim 10 has been withdrawn.

- **Rejection under 35 USC § 103(a) over Hutchinson (USPN 5,817,323):**

Applicant argued, "As acknowledged by the Examiner, Hutchison fails to teach a lipophilic vehicle having a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected, nor does it even suggest the importance of the relationship between the solubilizing power of the lipophilic vehicle and the concentration of the active substance at which taste is detected. In contrast, the present invention teaches that by specifically combining coated particles with a lipophilic vehicle tailored to that coating, as well as the active, improved taste-masking and stability of the coating may be achieved. This is not merely an obvious routine or manipulative experimentation during capsule formation, as alleged by the Examiner, but, as set forth in the subject specification, *inter alia,* in Example 4, superior results are achieved by tailoring the lipophilic vehicle according to the solubility of the active and coating therein."

Applicant's arguments have been fully considered but were not found persuasive. Admittedly, while Hutchinson does not explicitly teach that the "lipophilic vehicle has a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", a review of the instant specification (i.e., pages 5-6) and Applicant's remarks, establishes the "acceptable degree of solubilization of the drug/active substance is a function of drug loading and taste of the active" (p. 5, lines 19-20 of specification). The solubilization is also dependent upon various factors such as the particular taste of the drug/active substance, i.e., highly unpleasant taste versus less unpleasant taste (i.e., p. 6, lines 13-20 of specification). Based on this disclosure, one of ordinary skill in the art would be able to predict the level of solubility that is needed, dependent upon the particular active agent employed, in order to effect the resulting parameters of taste and taste perception. Moreover, the Examiner points out that the Hutchinson reference, nonetheless teaches active substances embedded within a fill composition that is comprised of the same components, i.e., hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking

purposes and stabilization of the suspensions - the exact same objective as instantly desired by Applicant. Hence, Applicant's argument that "improved taste-masking and stability of the coating may be achieved" was not persuasive since the formulations of Hutchinson meet this objective. The solubility characteristics or solubilization power argued by Applicant would be expected to be similar if not the same based on incorporation of the same ingredients (i.e., active ingredients) under similar conditions, absent a showing of evidence to the contrary. Furthermore, Applicant's argument that "In Example 4, superior results are achieved by tailoring the lipophilic vehicle according to the solubility of the active and coating therein", this argument has been considered but was not persuasive. As delineated above, Hutchinson teaches active substances embedded within a fill composition that is comprised of the same components, i.e., hydrophobic (lipophilic) components and provides for drug particles that can be coated for taste-masking purposes and stabilization of the suspensions; hence, the same objective as sought herein by Applicant. In addition, the Examples and Tables of the specification referenced by Applicant, i.e., Example 4, is more specific in scope as compared to the limitations of the instant claims, which are more generic in scope. The Tables/Examples are not representative of the scope of the claims being presented. The Tables/Examples provide for specific formulations, having specific active ingredients, specific lipophilic ingredients/oils, specific coating materials, all in specific amounts/concentrations and processed under specific formulation conditions, whereas the instant claims (at least claim 10) are generic in terms of the active agent employed, generic in terms of any concentration ranges/amounts and generic in terms of any lipophilic ingredients/oils. Thus, the instant claims do not parallel the specific Examples/Tables referenced

by Applicant. Accordingly, the instant claims, as presently recited, remain generic enough to read on the teachings of the Hutchinson reference, as discussed above.

This rejection has been maintained.

- **Rejections under 35 USC § 103(a) over Douglas (USPN 5,635,200) in view of Hutchinson ('323) and Ebert (USPN 4,532,126) in view of Hutchinson ('323):**

Applicant argued, "Douglas discloses compositions for masking the bitter taste of ranitidine, including coating ranitidine with a lipid. As acknowledged by the Examiner, Douglas fails to teach capsule shell components in the amounts claimed in the present invention. Ebert discloses a chewable soft gelatin capsule, which upon formation may be simultaneously filled with a fill material. As acknowledged by the Examiner, Ebert fails to teach coated crystals or granules of active agent in a lipophilic vehicle.

While the Examiner cites Hutchinson in combination with each of Douglas and Ebert, it is clear that all three references suffer from the same basic deficiency, namely the failure to teach or to suggest a lipophilic vehicle having a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected, as claimed in the present invention."

Applicant's arguments have been fully considered but were not found persuasive.

With respect the rejection of Douglas in view of Hutchinson, while Douglas fails to teach capsule shell components in the amounts as presently claimed, the Hutchinson reference clearly remedies this deficiency of Douglas. Hutchinson teaches soft gelatin capsule shell compositions comprising, *inter alia*, gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and unbleached starch, derivatives thereof or starch itself or mixtures thereof (column 1, lines 1-59); (col. 2, lines 17-30). Hutchinson explicitly teaches that the chewability of the capsules can be enhanced by inclusion of an oily component and plasticizers and teaches that their drug particles

may be separately coated, typically with suitably sweetened or flavored coatings, in order to provide for taste-masking effects as well as to impart stability to the capsule composition.

With respect the rejection of Ebert in view of Hutchinson, while Ebert fails to teach coated crystals or granules of active agent in a lipophilic vehicle as presently claimed, the Hutchinson reference clearly teaches coated drug particles that are provided in a hydrophobic (lipophilic) vehicle (col. 5, lines 61-67) and thus, remedies this deficiency of Ebert.

Applicant's argument that "all three references suffer from the same basic deficiency, namely the failure to teach or to suggest a lipophilic vehicle having a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected, as claimed in the present invention" has been considered, but was not rendered persuasive. As delineated above, with respect to the §103(a) rejection of Hutchinson alone, a review of the instant specification (i.e., pages 5-6) and Applicant's remarks, establishes the "acceptable degree of solubilization of the drug/active substance is a function of drug loading and taste of the active" (p. 5, lines 19-20 of specification). The solubilization is also dependent upon various factors such as the particular taste of the drug/active substance, i.e., highly unpleasant taste versus less unpleasant taste (i.e., p. 6, lines 13-20 of specification). Based on this disclosure, one of ordinary skill in the art would be able to predict the level of solubility that is needed, co-dependent upon factors, such as the particular active agent or taste of the drug/active substance employed, i.e., highly unpleasant taste versus less unpleasant taste, in order to effect the resulting parameters of taste and taste perception. The level or extent of solubility for the lipophilic vehicle would be adjustable based on the choice of active agent employed. In any event, the Hutchinson reference teaches active substances embedded within a

fill composition that is comprised of the same components, i.e., hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions - the exact same objective as instantly desired by Applicant. The solubility characteristics or solubilization power argued by Applicant would be expected to be similar if not the same based on incorporation of the same ingredients (i.e., active ingredients) under similar conditions, absent a showing of evidence to the contrary. Furthermore, note in particular, that the instant claims are generic, at least in terms of any specific active agent, amounts/ranges of active agent and also generic in terms of any particular coating materials employed. Accordingly, the instant claims, as presently recited, remain generic enough to read on the teachings of Douglas, Ebert and Hutchinson, as discussed above.

This rejection has been maintained.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

November 1, 2010